

September 15, 2006

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek N. Shenoy, Alonzo D. Cook and Scott Bruder

Application No.: 10/723,250

Group Art Unit: 1617

Filed: November 26, 2003

Examiner: Leonard M. Williams

Confirmation No.: 6059

Title: LOCAL INTRAOSSEOUS ADMINISTRATION OF BONE FORMING AGENTS
AND ANTI-RESORPTIVE AGENTS, AND DEVICES THEREFOR

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

9-18-06

Date

Amy T. Comeau

Signature

Amy T. Comeau

Typed or printed name of person signing certificate

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references [B20-B22, C117-C130] are enclosed.
 - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☒ The listed references [B20-B21, C117-C119, C123-C124] were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for references [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

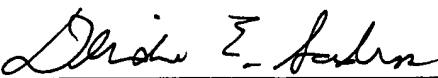
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 
Deirdre E. Sanders
Registration No.: 42,122
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: September 18, 2006

FD-1449 REPRODUCED

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

September 15, 2006

(Use several sheets if necessary)

 ATTORNEY DOCKET NO.
3518.1024-000

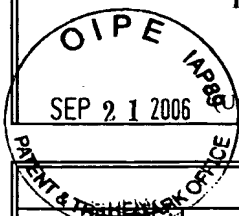
 APPLICATION NO.
10/723,250

 FIRST NAMED INVENTOR
Thomas M. DiMauro

 FILING DATE
November 26, 2003

 EXAMINER
Leonard M. Williams

 CONFIRMATION NO.
6059

 GROUP
1617

U.S. PATENT DOCUMENTS

| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER Number-Kind Code (if known) | ISSUE DATE / PUBLICATION DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
| | A45 | 6,756,215 B1 | 06-29-2004 | Wolfrain <i>et al.</i> |
| | A46 | 5,194,596 | 03-16-1993 | Tischer <i>et al.</i> |
| | A47 | 2002/0082697 A1 | 06-27-2002 | Damien |
| | A48 | 2004/0022864 A1 | 02-05-2004 | Freyman <i>et al.</i> |
| | A49 | 2004/0126372 A1 | 07-01-2004 | Banerjee <i>et al.</i> |
| | A50 | 6,340,369 B1 | 01-22-2002 | Ferree |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER Country Code-Number-Kind Code (if known) | DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT | TRANSLATION YES NO | |
|--|-----|--|--------------------|--|-----------------------|--|
| | B20 | WO 2005/110276 A1 | 11-24-2005 | Massachusetts General Hospital | | |
| | B21 | WO 2005/000283 A2 | 01-06-2005 | DePuy Spine, Inc. | | |
| | B22 | WO 2006/031376 A2 | 03-23-2006 | DePuy Spine, Inc. | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|------|--|
| | C117 | Hawks, D., "Alternative Medicine: Musculoskeletal System," <i>Clin. Tech. Small Anim. Pract.</i> , 17(1):41-49 (2002). |
| | C118 | Khot, A. <i>et al.</i> , "The Use of Intradiscal Steroid Therapy for Lumbar Spinal Discogenic Pain - A Randomized Controlled Trial," <i>Spine</i> , 29(8):833-837 (2004). |
| | C119 | Földes, I. <i>et al.</i> , "Trace Elements in Tissues of Normal and Vitamin D ₂ -Treated Rats," <i>ACTA Biol. Acad. Sci. Hung.</i> , 26(3-4):141-150 (1975). |
| | C120 | Benjamin, L.E. <i>et al.</i> , "A Plasticity Window for Blood Vessel Remodelling is Defined by Pericyte Coverage of the Preformed Endothelial Network and is Regulated by PDGF-B and VEGF," <i>Development</i> , 125:1591-1598 (1998). |
| | C121 | Vukicevic, S. <i>et al.</i> , "Induction of Nephrogenic Mesenchyme by Osteogenic Protein 1 (Bone Morphogenetic Protein 7)," <i>Proc. Natl. Acad. Sci.</i> , 93:9021-9026 (1996). |

EXAMINER

DATE CONSIDERED

| | | | | |
|---|---|--|----------------------------------|---------------|
| P7-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 15, 2006 (Use several sheets if necessary) | ATTORNEY DOCKET NO. 3518.1024-000 | | APPLICATION NO. 10/723,250 | |
| | FIRST NAMED INVENTOR Thomas M. DiMauro | | FILING DATE November 26, 2003 | |
| | EXAMINER Leonard M. Williams | | CONFIRMATION NO. 6059 | GROUP 1617 |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|--|---|--|
| C122 | Moreira, A.L. <i>et al.</i> , "Thalidomide Exerts Its Inhibitory Action on Tumor Necrosis Factor α by Enhancing mRNA Degradation," <i>J. Exp. Med.</i> , 177:1675-1680 (1993). | |
| C123 | CN 1 647 808 A (Zhou C) 2005-08-03 (abstract) World Patents Index [online]. London, GB: Derwent Publications, Ltd., Week 200621, Class B04, Accession No. 2006-194507. | |
| C124 | CN 1 569 039 A (Niu X) 2005-01-26 (abstract) World Patents Index [online]. London, GB: Derwent Publications, Ltd., Week 200577, Class B04, Accession No. 2005-749289. | |
| C125 | Shiel, W.C., Ankylosing Spondylitis, MedicineNet.com [online], September 2005 [retrieved on 2006-06-20]. Retrieved from the Internet <URL: http://www.medicinenet.com/script/main/art.asp?articlekey=274&pf=3&page=2 >. | |
| C126 | Sampaio, E.P. <i>et al.</i> , "Thalidomide Selectively Inhibits Tumor Necrosis Factor α Production by Stimulated Human Monocytes," <i>J. Exp. Med.</i> , 173:699-703 (1991). | |
| C127 | Muller, G.W. <i>et al.</i> , "Amino-Substituted Thalidomide Analogs: Potent Inhibitors of TNF- α Production," <i>Bioorg. Med. Chem. Lett.</i> , 9:1625-1630 (1999). | |
| C128 | Teo, S.K., "Properties of Thalidomide and its Analogues: Implications for Anticancer Therapy," <i>AAPS Journal</i> 7(1):E14-E19 (2005). | |
| C129 | Crevensten, G. <i>et al.</i> , "Intervertebral Disc Cell Therapy for Regeneration: Mesenchymal Stem Cell Implantation in Rat Intervertebral Discs," <i>Ann. Biomed. Eng.</i> , 32(3):430-434 (2004). | |
| C130 | Tracey, K.J. and Cerami, A., "Tumor Necrosis Factor in Metabolism of Disease: Hormonal Actions Versus Local Tissue Effects," <i>Nouv. Rev. Fr. Hematol.</i> , 34 Suppl:S37-42 (1992) (abstract). | |

| | |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|